

[0018] SEQ ID NO:7 is a polypeptide sequence for L523S.

[0019] SEQ ID NO:8 is a polypeptide sequence for L523S p13-21.

## DETAILED DESCRIPTION OF THE INVENTION

### I. Introduction

5 [0020] The present invention provides compositions that can target a malignancy with which a particular cancer antigen is associated, and compositions and methods that can elicit and enhance an immune response to the particular cancer antigen. In particular, the invention provides an expression vector DNA plasmid that can express genes when transfected into eukaryotic cells. The vector comprises an expression cassette comprising from 5' to 3' the  
10 following elements: a CMV promoter sequence, a CMV enhancer sequence, a CMV intron A sequence from the CMV major immediate early gene, a heterologous nucleic acid sequence, and a polyadenylation site, wherein the promoter is operably linked to the heterologous nucleic acid sequence. In an exemplary embodiment, the heterologous nucleic acid sequence is a cancer antigen. In some embodiments, the heterologous nucleic acid sequence encodes a  
15 cancer antigen. The invention also provides compositions comprising the expression vector and pharmaceutically acceptable carrier. The invention further provides compositions for expressing the heterologous nucleic acid sequence and methods for eliciting an immune response against the polypeptide encoded by the heterologous nucleic acid sequence by administering such compositions to a subject.

### 20 II. Definitions

[0021] An "immunogenic composition" is one that elicits or modulates an immune response, preferably the composition induces or enhances an immune response in response to a particular antigen. Immune responses include humoral immune responses and cell-mediated immune responses. An immunogenic composition can be used therapeutically or  
25 prophylactically to treat or prevent disease at any stage.

[0022] As used herein, "heterologous" is defined in relation to a predetermined referenced nucleic acid or amino acid sequence. For example, with respect to a structural gene sequence, a heterologous promoter is defined as a promoter which does not naturally occur adjacent to the referenced structural gene, but which is positioned by laboratory

## EXAMPLES

### Example 1: Construction of pCRXA-20

[0214] The plasmid pCRXA20 was constructed using (1) a plasmid origin of replication derived from pUC9; (2) a kanamycin resistance gene and bacterial promoter cloned from pRSVneo; (3) a SV40 polyadenylation sequence cloned from pRSVneo, (4) a CMV promoter and (5) a 5 prime untranslated sequence of the MIE region containing a portion of Intron A, Exon A and part of Exon B cloned from human Cytomegalovirus.

[0215] pCRXA20 (SEQ ID NO:3) is 3584 bases and comprises 5 regions. The first region (bases 1-1368) was cloned from viral DNA of the human CMV virus, Towne strain(ATCC Number: VR-977). This first region contains the viral promoter, enhancer, and intron A, corresponding to bases 512-1513 and 1736-2094 of the major-immediate early gene of CMV (Genbank Accession No. M60321) and drives the mRNA transcription of a cloned gene. The second region (bases 1369-1416) contains recognition sites for 6 restriction enzymes and was derived from annealed oligonucleotides. This region allows for cloning of a gene into the vector. The third region (bases 1417-1651) was cloned from bases 3407-3634 of the plasmid pRSVneo (ATCC# 37198). This third region contains the early and late polyadenylation signals of the SV40 virus and provides the necessary polyA sites for the mRNA transcript of a cloned gene. The fourth region (bases 1652-2581) contain a bacterial promoter and the gene for Kanamycin resistance. The promoter was cloned from bases 2463-2600 of the plasmid pUC9 (ATCC# 37252), and bases 4589-5383 of the gene from pRSVneo. This fourth region allows for the selective growth of bacteria containing the vector. The fifth region (bases 2582-3584) contain an origin of replication, cloned from to bases 605-1600 of pUC9 and allows for the propagation of the vector in bacteria.

### Example 2: Induction of Immune Response Using pCRXA-20

[0216] A replication defective E1 and E3 deleted human adenovirus serotype 5 vector expressing human L523S under the control of the CMV promoter was generated using standard molecular biology techniques (AdEasy System, Johns Hopkins University, Baltimore, MD). The DNA sequence of the L523S-Adenovirus- vector is set forth in SEQ ID NO:5. The cDNA sequence encoding the full-length L523S protein is set forth in SEQ ID NO:6 with the corresponding amino acid sequence set forth in SEQ ID NO:7.

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